Magic Wallstent® Endoprosthesis
SUMMARY of SAFETY and EFFECTIVENESS DATA

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SUMMARY of SAFETY and EFFECTIVENESS DATA
Magic Wallstent® Endoprosthesis

1 General Information

Device Generic Name:	Intravascular Stent
Device Trade Name:	Magic Wallstent® Endoprosthesis
Applicant's Name and Address:	Schneider (USA) Inc Pfizer Medical Technology Group 5905 Nathan Lane, Minneapolis, MN 55442
PMA Number:	P980009

Date of Notice of Approval to the Applicant: September 29, 1998

2 Indications and Usage

The Magic Wallstent® Endoprosthesis is indicated for improving luminal diameter in the following:

- patients with symptomatic ischemic disease due to discrete de novo lesions in native coronary arteries (length ≤ 35 mm) with a reference vessel diameter of 3.0 to 5.5 mm;
- treatment of abrupt or threatened closure in patients with failed interventional therapy in lesions with reference diameters in the range of 3.0 to 5.5 mm.

3 Contraindications

The Magic Wallstent® Endoprosthesis is contraindicated for use in:

- Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated.
- Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon.

4 Warnings and Precautions

See WARNINGS AND PRECAUTIONS in the final draft labeling (Information for Use)

5 Device Description

The Magic Wallstent® Endoprosthesis includes: a stent composed of a biomedical superalloy wire with a radiopaque platinum alloy core. It is braided in a tubular mesh configuration and premounted on an over-the-wire delivery catheter which allows reconstrainment of the stent (when deployed ≤ 50%). Radiopaque markers on the delivery catheter aid in the accurate placement of the stent.

MRI Safe: The Magic Wallstent® Endoprostheses have shown no deflection or torque in the area of maximum spatial gradient (450 gauss centimeter) of a 1.5 tesla MRI system under conditions that produced a Specific Absorption Rate (SAR) of 1.3 W/kg. Imaging artifacts affect the region of interest at the location of the device (artifact ratio 1.2 to 6.7), while areas away from the device appear unaffected by their presence.

The device includes the following models. All require a minimum 0.064 inch guiding catheter lumen.

Table 5.1. Stent Models Available

Model #	Stent Length Descriptor	Stent Nominal Diameter	Stent Constrained Length	Model #	Stent Length Descriptor	Stent Nominal Diameter	Stent Constrained Length
MAG-64490	mini	3.5 mm	14 mm	MAG-64513	long	4.5 mm	60 mm
MAG-64491	extra short	3.5 mm	20 mm	MAG-64520	short	5.0 mm	30 mm
MAG-64492	short	3.5 mm	30 mm	MAG-64521	medium	5.0 mm	40 mm
MAG-64493	medium	3.5 mm	40 mm	MAG-64522	long	5.0 mm	60 mm
MAG-64500	extra short	4.0 mm	20 mm	MAG-64530	short	5.5 mm	30 mm
MAG-64501	short	4.0 mm	30 mm	MAG-64531	medium	5.5 mm	40 mm
MAG-64502	medium	4.0 mm	40 mm	MAG-64532	long	5.5 mm	60 mm
MAG-64503	long	4.0 mm	60 mm	MAG-64544	short	6.0 mm	30 mm
MAG-64510	extra short	4.5 mm	20 mm	MAG-64541	medium	6.0 mm	40 mm
MAG-64511	short	4.5 mm	30 mm	MAG-64542	long	6.0 mm	60 mm
MAG-64512	medium	4.5 mm	40 mm				

6 Alternative Practices or Procedures

Alternative procedures include percutaneous transluminal coronary angioplasty (PTCA), coronary bypass graft surgery and other commercially available stents.

7 Marketing History

The Magic Wallstent® Endoprosthesis has been commercially distributed since October 1996. The device is available for commercial sale in the European community (CE Mark, certification #01073), Australia, Canada, Brazil and Argentina.

The Magic Wallstent® Endoprosthesis was voluntarily withdrawn worldwide in March 1997 because of three reported bond separations in the delivery catheter, in which the distal section of the delivery catheter separated. The entire delivery catheter was

successfully removed in all three cases with no adverse consequences to the patients. The bond was redesigned and validated. Commercial distribution resumed in June 1997. The units used for the Magic Registry in the WIN Trial were manufactured with the redesigned bond.

8 Adverse Events

8.1 Observed Adverse Events

A total of 893 patients were enrolled in two multi-center studies, the WIN Trial and Wellstent Registry. Patients from the WIN Randomized Trial (N=586) form the basis of the major adverse events listed in Table 8.1

Table 8.1. Adverse Events during the First 6 Months
% [± 95% Confidence Interval] (Number) All patients in randomized trial (n=586)

Adverse Event	Wallstent® Endoprosthesis (n=299)	PTCA (n=287)	Difference [95% CI]
ANY Adverse Event	27.8% [22.8%, 33.2%] (83)	26.5% [21.5%, 32.0%] (76)	1.3% [-5.9%, 8.5%]
Early (in-hospital)	15.7% [11.8%, 20.3%] (47)	11.8% [8.3%, 16.2%] (34)	3.9% [-1.7%, 9.4%]
Out- of-hospital	12.7% [9.2%, 17.0%] (38)	15.3% [11.4%, 20.0%] (44)	-2.6% [-8.2%, 3.0%]
Non-Q-wave MI Total	6.0% [3.6%, 9.3%] (18)	3.8% [1.9%, 8.8%] (11)	2.2% [-1.3%, 5.7%]
Early (In-hospital)	5.4% [3.1%, 8.5%] (16)	3.8% [1.9%, 6.8%] (11)	1.5% [-1.9%, 4.9%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0% [0.0%, 1.3%] (0)	0.7% [-0.3%, 1.6%]
Q-wave MI Total	2.3% [0.9%, 4.8%] (7)	2.1% [0.8%, 4.5%] (6)	0.3% [-2.1%, 2.6%]
Early (in-hospital)	1.7% [0.5%, 3.9%] (5)	1.4% [0.4%, 3.5%] (4)	0.3% [-1.7%, 2.3%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0.7% [0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
CABG Total	1.3% [0.4%, 3.4%] (4)	1.0%[0.2%, 3.0%] (3)	0.3% [-1.5%, 2.0%]
Early (in-hospital)	0.7% [0.1%, 2.4%] (2)	0.7%[0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
Out-of-hospital	0.7% [0.1%, 2.4%] (2)	0.3% [0.0%, 1.9%] (1)	0.3% [-0.8%, 1.5%]
Stent Thrombosis Total	1.7% [0.5%, 3.9%] (5)	0.7% [0.1%, 2.5%] (2)	1.0% [-0.8%, 2.7%]
Early (in-hospital)	1.3% [0.4%, 3.4%] (4)	0% [0.0%, 1.3%] (0)	1.3% [0.0%, 2.6%]
Out-of-hospital	0.3% [0.0%, 1.8%] (1)	0.7% [0.1%, 2.5%] (2)	-0.4% [-1.5%, 0.8%]
Death Total	2.3% [0.9%, 4.8%] (7)	1.7% [0.6%, 4.0%] (5)	0.6% [-1.7%, 2.9%]
Early (in-hospital)	0% [0.0%, 1.2%] (0)	0.7% [0.1%, 2.5%] (2)	-0.7% [-1.7%, 0.3%]
Out-of-hospital	2.3% [0.9%, 4.8%] (7)	1.0% [0.2%, 3.0%] (3)	1.3% [-0.8%, 3.4%]
Bleeding Complications	4.0% [2.1%, 6.9%] (12)	1.7% [0.6%, 4.0%] (5)	2.3% [-0.4%, 5.0%]
Vascular Complications	7.7% [4.9%, 11.3%] (23)	8.4% [5.4%, 12.2%] (24)	-0.7% [-5.1%, 3.7%]
Cerebrovascular Accidents	0.7%[0.1%, 2.4%] (2)	0.7% [0.1%, 2.5%] (2)	0% [-1.4%, 1.3%]
Stent Delivery Failures	7.7% [4.7%, 10.7%] (23)	5.7% [1.3%, 10.2%] (6/105)	2.0% [-3.4%, 7.3%]

***Early (in-hospital)** refers to events during the hospitalization for the initial stent placement.*

In cases where a patient experienced both an in-hospital event and an out-of-hospital event, they are counted once in each group, but only once in the event total. Hence, the sum of the in-hospital event rate and the out-of-hospital event rate may not equal the total event rate.

***ANY Major Adverse Event** includes death, Q wave MI, non-Q wave MI, emergent CABG, target lesion revascularization, stent thrombosis, bleeding complications, vascular complications and CVA*

***Stent Delivery Failures:** stent misplacement, unable to cross lesion, unable to reach lesion*

Nine patients who received the Wallstent® Endoprosthesis died during the WIN Randomized Trial. Seven of these deaths occurred during the first six months and are included in Table 8.1. Of the nine deaths, one death occurred within 30 days of stenting, but after hospital discharge, due to cardiac arrest. Eight deaths occurred between 67 and

433 days due to arrhythmia (n=4), cardiac arrest (n=1), encephalopathy (n=1), cancer (n=1) and unknown (n=1).

Two patients died during the Feasibility study. Both deaths occurred between 250 and 357 days due to sudden death (n=1) and cancer (n=1). No deaths occurred in the Magic and Post-randomization Registry.

8.2 Potential Adverse Events

Adverse events (in alphabetical order) which may be associated with the use of a coronary stent in coronary vessels (including those listed in Table ?2):

- Acute myocardial infarction
- Arrhythmias, including VF and VT
- Death
- Dissection
- Drug reactions to antiplatelet agents/contrast medium
- Emboli, distal (air, tissue, or thrombotic emboli)
- Emergent coronary artery bypass surgery
- Hemorrhage, requiring transfusion
- Hypotension/hypertension
- Infection and/or pain at the access site
- Ischemia, myocardial
- Perforation
- Pseudoaneurysm, femoral
- Restenosis of stented segment
- Spasm
- Stent embolization
- Stent thrombosis/occlusion
- Stroke/cerebrovascular accident
- Total occlusion of coronary artery

9 Summary of Preclinical Studies

9.1 Biocompatibility

Biocompatibility of the stent and the delivery system were tested in accordance with the FDA-modified matrix of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The following tests were conducted: cytotoxicity, sensitization, irritation, systemic toxicity, implantation, hemocompatibility, hemolysis, mutagenicity, and pyrogenicity. The results of all biocompatibility tests were acceptable.

9.2 Bench Testing

Stent Material Composition Conformance

The chemical composition of the biomedical superalloy wire conforms to the ASTM 1058 standard and the composition of the platinum alloy core conforms to the ASTM B561 and ASTM B39 standards.

Stent Wire Mechanical Properties Conformance

The mechanical properties (tensile strength and elongation) of the stent wire were documented through tensile testing.

Corrosion Resistance

To determine the corrosion resistance of the stent wire, six samples were tested in

accordance with the ASTM F746 and ASTM G5 standards. The results indicated that the stent has a very high resistance to pitting corrosion and the potential for galvanic corrosion was considered low.

Stent Percent Free Area
The percent free area, i.e. area not in contact with the vessel wall, was calculated for all of the stent sizes. The results found that the percent free area ranged from 81% to 83%.

Stent Dimensional Verification
To determine the dimensional conformity of the stent, the outer diameter, and constrained and unconstrained stent length were measured for 8-20 samples of the 3.5 mm, 4.0 mm and 6.0 mm diameter stents. The average outer diameter deviated less than 0.3 mm from the nominal stent diameter and the constrained and unconstrained stent lengths were within the test specifications.

Radial Force
The force exerted by the self-expanding stent as a function of its diameter was measured in eight 4.0 mm diameter and eight 6.0 mm diameter stents. The average force for both sizes ranged from 0.01 to 0.02 lbs for vessels 0.5 mm to 1 mm smaller than the stent. These results were considered acceptable.

Fatigue
Finite element stress analyses was performed on all stent sizes. The analysis included fabrication stresses and the calculation of peak stress as a function of diameter, ranging from fully constrained (loaded on the catheter) to unconstrained (fully deployed). The stress analyses indicated a satisfactory safety factor was present and fatigue failure of the stent was unlikely.

Magnetic Resonance Imaging (MRI) CompatibilityTesting
MRI compatibility testing determined the location of the maximum spatial gradient within the scanner and measured the average deflection for each stent from the displacement force and from the displacement torque. The change in temperature of the stent was measured during a pulse sequence that produced a whole body averaged specific absorption rate of 1.3W/kg. Geometric distortion was calculated under a gradient pulse echo sequence and a conventional spin echo pulse sequence. The results found that the stent was MRI safe with artifact affecting imaging at the location of the stent.

Delivery Catheter Crossing Profile
To verify the crossing profile, the outer diameter of 78 stents, representing all of the stent diameter sizes, was measured at the maximum outer diameter point. All of the measurements were within the test specification.

Delivery Catheter Trackability
To determine the amount of force necessary to pass a delivery catheter with mounted stent over a guidewire, six to seven of the smallest and largest stent sizes were tested in a

simulated clinical model. The results found that the tracking forces were acceptable.

Delivery Catheter Stent Deployment Force
To determine the force required to deploy and reconstrain the stent, six to seven of the smallest and largest stent sizes were tested in a simulated clinical model. All of the samples were within the test specification.

Delivery Catheter Bond Strength
To demonstrate the strength of the bonded joints, tensile testing was performed on a minimum of 26 samples for each of the bonded locations. The results found that the strength of each of the bonded joints exceeded the test specification.

9.3 Sterility and Packaging Testing

Sterility
The Magic Wallstent Endoprosthesis is sterilized by a validated gamma radiation process. The validated protocol was based on the AAMI/ANSI ST 32-1991 "Guideline for Gamma Radiation Sterilization", Methods 3A and 3B. The validation results demonstrated that the sterilization process achieved a sterility assurance level of 10-6.

Shipping and Shelf-Life Tests
Shipping tests in accordance with the ASTM D4169-94 Standard Practice for Performance Testing of Shipping Containers and Systems were conducted on 84 samples accelerated aged for an equivalent of 3.5 years. Twenty-four of the samples were exposed to a microbial challenge test and tested for sterility. All of the samples were found to be sterile. The results of peel testing (n=30) and burst testing (n=30) conducted on the packaging found that all samples were within the test specification. Bond strength and functionality testing were conducted on 15 additional samples accelerated aged out to 3.5 years and exposed to shipping stresses. All of the samples were within the test specification. Based on these results a shelf life of 3.5 years has been established.

10 Summary of Clinical Studies

A total of 893 patients were treated at 26 North American investigational sites in the four parts of the WIN Trial and at 11 European investigational sites in the Wellstent Registry (Table 10.1). The WIN Trial is summarized below.

Table 10.1. Patient Enrollment in Clinical Studies
All patients in all studies (n=893)

	Wallstent® Endoprosthesis	PTCA	Patient Totals
Wellstent Registry (Europe)	105	-	105
WIN (Wallstent in Native) Trial			
Feasibility Study	132	-	132
WIN Randomized Trial	299	287	586
Post-randomization Registry	15	-	15
Magic Registry	55	-	55
PATIENT TOTALS	606	287	893

Primary Endpoint: The primary endpoint for the WIN Trial was MACE+CVA at 6 months. MACE+CVA was defined as a composite of death, nonfatal myocardial infarction, CVA, and clinically driven target lesion revascularization. An independent clinical events committee (CEC), adjudicated all of the major clinical endpoints.

Patients Studied: Eligible patients were candidates for percutaneous transluminal coronary angioiplasty (PTCA) with ischemic coronary artery disease and one or two de novo or restenotic lesions in native coronary arteries with maximum vessel diameter of 3.0 to 5.5 mm and lesion length ≤ 22 mm (3.0 mm – 4.0 mm vessels) or ≤ 35 mm (4.1 mm – 5.5 mm vessels).

Methods: In the WIN Randomized Trial, patients were prospectively randomized to treatment with the Wallstent® Endoprosthesis or PTCA. The patients underwent balloon angioplasty with an appropriate balloon diameter matching the reference vessel diameter. Post-stent deployment dilation with a high pressure, non-compliant balloon (balloon to artery ratio of 1:1) was recommended to hasten expansion of the stent. The goal was a residual stent diameter stenosis of less than 10%.

Patients in the PTCA arm received secondary treatment if acute results met one or more of the following abrupt or threatened closure conditions: TIMI flow < 3 which persisted after treatment with PTCA balloon and was related to mechanical dissection, or ≥ 50% residual stenosis, or any dissection grade C or higher.

Clinical follow-up was performed at 6 weeks, six months and one year. Six-month angiographic follow-up was requested of all patients. Anticoagulation included aspirin 325-mg/day for at least one year for all patients. Stent patients also received ticlopidine 500-mg/day for 30 days. If optimal results (≤ 10% residual stenosis) were not achieved at stent implantation, the physician had the option to add an antithrombin agent.

Results: Of the 299 patients randomized to the Wallstent® Endoprosthesis in the WIN Randomized Trial there were 256 patients with de novo lesions and 43 patients with restenotic lesions. Baseline characteristics were similar for the two treatment groups in the

randomized trial. All patients were included in the intent-to-treat effectiveness analysis. The MACE+CVA rate at 6 months was 24% for patients with de novo lesions and 14% for patients with restenotic lesions with an associated difference of 10% and 95% confidence interval of [-2.1%, 21%]. Table 10.2 shows the results for both groups (restenosis and de novo lesions combined). Figure 1 shows the actuarial freedom from MACE+CVA.

Table 10.2. Principal Effectiveness and Safety Results
All Patients in the WIN Randomized Trial (n=586)

Effectiveness Measures	Wallstent® Endoprosthesis (n=299)	PTCA (n=287)	Difference [95% CI]
Device Success	96% (286/298)	60% (158/265)	36%* [30%, 43%]
Procedure Success	97% (289/298)	96% (258/268)	0.7% [-2.3%, 3.7%]
Post-procedure In-Lesion %DS	19% ± 13% (298)	26% ± 13% (268)	-7.1%* [-9.2%, -4.9%]
Range (min, max)	(-26%, 98%)	(-11%, 100%)	
6 Months Follow-up In-Lesion %DS	45% ± 20% (229)	46% ± 20% (196)	-0.9% [-4.8%, 2.9%]
Range (min, max)	(-1%, 100%)	(5%, 100%)	
6 Months Follow-up In-Lesion Binary Restenosis Rate	38% (87/229)	38% (75/196)	-0.3% [-9.5%, 9.0%]
TLR-free at 6 Months (K-M)	87% [83%, 91%]	85% [81%, 90%]	1.8% [-3.9%, 7.5%]
TVR-free at 6 Months (K-M)	84% [80%, 89%]	84% [79%, 88%]	0.9% [-5.2% 7.0%]
MACE+CVA-free at 6 Months (K-M)	80% [75%, 84%]	80% [75%, 85%]	-0.4% [-6.9%, 6.2%]
MACE+CVA rate at 6 Months	20% (60/294)	20% (56/279)	0.3% [-6.2%, 6.9%]
Safety Measures			
In-Hospital Major Clinical Events	8.0% (24/299)	5.9% (17/287)	2.1% [-2.0%, 6.2%]
Out-of Hospital Major Clinical Events	12.0% (36/299)	13.9% (40/287)	-1.9% [-7.3%, 3.5%]
Bleeding Complications	4.0% (12/299)	1.7% (5/287)	2.3% [-0.4%, 5.0%]
Vascular Complications	7.7% (23/299)	8.4% (24/287)	-0.7% [-5.1%, 3.7%]
Stent Thrombosis	1.7% (5/299)	1.9% (2/105)	-0.2% [-3.2%, 2.8%]
Subacute Closure	1.3% (4/299)	1.4% (4/287)	-0.1% [-1.9%, 1.8%]

Numbers are % (counts/sample size) or Mean ± standard deviation. CI is Confidence Interval. RR is relative risk.
Device Success: attainment of < 50% residual stenosis using assigned device without using a device outside the assigned treatment strategy.
Procedure Success: < 50% residual stenosis and freedom from in-hospital death, Q-wave MI, or emergent CABG.
%DS: percent diameter stenosis; TLR: target lesion revascularization; TVR: target vessel revascularization
CVA: cerebral vascular accident; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG)
***Major Clinical Event**: death, MI, TLR (PTCA or CABG) or CVA*
***Subacute closure**: abrupt closure occurring after index procedure completed and patient out of catheterization laboratory, but within 30 days.*
***Stent thrombosis**: total thrombotic stent occlusion documented by angiography or cardiac death occurring in the first 30 days after stenting.*
***Bleeding complications**: transfusion of blood products due to blood loss resulting from the percutaneous revascularization procedure, or blood loss resulting in change in anticoagulation regimen.*
***Vascular complications**: occurrence of hematoma, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure-related transfusion, and vascular surgical repair.*
K-M indicates Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.
** Difference statistically significant (p<0.05) by Chi square or t-test*

Secondary treatment was necessary in a high percentage of patients in the PTCA group (105, 37%). Secondary treatment in all cases was stent implantation (71 Wallstent® Endoprosthesis, 31 other stents, and 3 unsuccessful stenting attempts). Baseline patient variables were similar between the two subgroups. Lesion length (mean ± SD) was significantly different (13 ± 6 mm for PTCA Only group, 17 ± 10 mm for PTCA+Stent

group, p<0.0001). In the PTCA+Stent group, the MACE+CVA rate at 6 months was 24% for patients with the Wallstent® Endoprosthesis and 23% for patients with other stents, with an associated difference of 0.8% and 95% confidence interval of [-6.1%, 7.7%]. Table 10.3 shows the results for PTCA Only vs. all secondary treatment cases combined.

Table 10.3. Principal Effectiveness and Safety Results
All Patients in the WIN Randomized Trial PTCA Group (n=287)

Effectiveness Measures	PTCA Only (n=182)	PTCA + Stent (n=105)	Difference [95% CI]
Device Success	96% (158/165)	0% (0/100)	96%* [93%, 99%]
Procedure Success	95% (159/167)	98% (99/101)	-2.8% [-7.0%, 1.4%]
Post-procedure In-Lesion %DS	30% ± 12% (167)	19% ± 12% (101)	11%* [8.2%, 14%]
Range (min, max)	(2%, 100%)	(-11%, 56%)	
6 Months Follow-up In-Lesion %DS	45% ± 19% (128)	47% ± 22% (68)	-1.8% [-7.8%, 4.2 %]
Range (min, max)	(5%, 100%)	(12%, 100%)	
6 Months Follow-up In-Lesion Binary Restenosis Rate	39% (50/128)	37% (25/68)	2.3% [-12%, 17%]
TLR-free at 6 Months * (K-M)	87% [82%, 92%]	83% [75%, 91%]	3.6% [-5.1%, 12%]
TVR-free at 6 Months * (K-M)	85% [80%, 90%]	81% [73%, 89%]	3.9% [-5.2%, 13%]
MACE+CVA-free at 6 months * (K-M)	82% [76%, 88%]	77% [68%, 85%]	5.2% [-4.6%, 15%]
MACE+CVA rate at 6 Months	18% (32/177)	24% (24/102)	-5.5% [-15%, 4.5%]
Safety Measures			
In-Hospital Major Clinical Events	3.8% (7/182)	9.5% (10/105)	-5.7%[-12%, 0.6%]
Out-of Hospital Major Clinical Events	13.7% (25/182)	14.3% (15/105)	-0.5% [-8.9%, 7.8%]
Bleeding Complications	1.6% (3/182)	1.9% (2/105)	-0.3% [-3.5%, 2.9%]
Vascular Complications	8.8% (16/182)	7.6% (8/105)	1.2% [-5.4%, 7.7%]
Stent Thrombosis	0% (0/182)	1.9% (2/105)	-1.9% [-4.5%, 0.7%]
Subacute Closure	1.1% (2/182)	1.9% (2/105)	-0.8% [-3.8%, 2.2%]

Numbers are % (counts/sample size) or Mean ± standard deviation. CI is Confidence Interval. RR is relative risk.

***Device Success**: attainment of < 50% residual stenosis using assigned device without using a device outside the assigned treatment strategy.*

***Procedure Success**: attainment of < 50% residual stenosis and freedom from in-hospital death, Q-wave MI, or emergent CABG.*

%DS: percent diameter stenosis; K-M: Kaplan-Meier estimate; TLR: target lesion revascularization; TVR: target vessel revascularization

CVA: cerebral vascular accident; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG)

***Major Clinical Event**: death, Q-wave or non-Q-wave MI, TLR (PTCA or CABG) or CVA*

***Subacute closure**: abrupt closure occurring after index procedure completed and patient out of catheterization laboratory, but within 30 days.*

***Stent thrombosis**: total thrombotic stent occlusion documented by angiography or cardiac death occurring in the first 30 days after stenting.*

***Bleeding complications**: transfusion of blood products due to blood loss resulting from the percutaneous revascularization procedure, or blood loss resulting in change in anticoagulation regimen.*

***Vascular complications**: occurrence of hematoma, false aneurysm, AV fistula, retroperitoneal bleed, peripheral ischemia/nerve injury, procedure-related transfusion, and vascular surgical repair.*

K-M indicates Survival estimates by Kaplan-Meier method; Standard Error estimates by Greenwood formula.

** Difference statistically significant (p<0.05) by Chi square or t-test*

Lesion length was a significant predictor for some measures of clinical restenosis in both arms (see 7.1 Individualization of Treatment). The MACE+CVA rate at 6 months was 20% for the Wallstent® Endoprosthesis group and 20% for the PTCA group with an associated difference of 0.3% and 95% confidence interval of [-6.2%, 6.9%]. Lesion

length (mean ± SD) was 15 ± 9 mm for the Wallstent® Endoprosthesis group and 14 ± 8 mm for the PTCA group with an associated difference of 1 and 95% confidence interval of [-0.4, 2.4]. Relationships between lesion length and major effectiveness/safety measures at six months for all patients in the WIN Randomized Trial are shown in Table 10.4.

Table 10.4. Lesion Length Analysis, WIN Randomized Trial
(Wallstent® Endoprosthesis + PTCA)
All Patients in the WIN Randomized Trial (n=586)

Effectiveness/Safety Measures at 6 Months	Lesion Length (0-10 mm)	Lesion Length (11-20 mm)	Lesion Length (>20 mm)
%DS in-lesion	41% ± 19%	47% ± 20%	51% ± 21%
Binary Restenosis rate in-lesion	28% (41/149)	42% (88/208)	49% (33/67)
TLR	16% (33/209)	25% (67/271)	27% (25/94)
TVR	21% (44/209)	29% (78/271)	31% (29/94)
MACE	23% (49/209)	32% (87/271)	36% (34/94)

TLR: target lesion revascularization; TVR: target vessel revascularization; MACE: death, Q-wave or non-Q-wave MI, TLR (PTCA/CABG)

The WIN Trial (N=788) included the WIN Randomized Trial (N=586) and Magic Registry (N=55). The Magic Registry was conducted to demonstrate the safety through discharge of the new over-the-wire Magic delivery system as compared to the rolling membrane over-the-wire delivery catheter used in the WIN Randomized Trial. The in-hospital rate for any major clinical event was 5.5% in the Magic Registry, compared with 8.0% for Wallstent® Endoprosthesis group in the WIN Randomized Trial, difference 2.6% [-4.2%, 9.3%].

11 Conclusions Drawn from Studies

The preclinical studies indicate that the system meets or exceeds safety, reliability and performance specifications.

Multicenter clinical data show that the Magic Wallstent® Endoprosthesis is comparable to a U.S. commercially available coronary stent (control stent) in the treatment of abrupt and threatened closure and *de novo* native coronary artery lesions.

The preclinical testing information and the results of the randomized clinical trial provide valid scientific evidence and reasonable assurance that the Magic Wallstent® Endoprosthesis is safe and effective when used in accordance with its labeling.

12 Panel Recommendations

In accordance with the provisions of section 515©(2) of the Federal Food, Drug and Cosmetic Act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates

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information previously reviewed by this panel.

13 FDA Decision

The FDA issued an approval order on September 29, 1998.

A condition of the sale of the device was the further characterization of long-term safety and effectiveness through continued follow-up of the patients implanted with the Wallstent Endoprosthesis in the WIN Trial. Patients were to be followed for five years from implant. The protocol for the continued follow-up was to be submitted to the Agency for review within 30 days of approval.

The applicant's manufacturing facility was inspected and was found to be in compliance with the device Good Manufacturing Practice Regulations.

14 Approval Specifications

Directions for Use: See the labeling.

Hazards to Health from User of the Device: See INDICATIONS, CONTRAINDICATIONS,WARNINGS AND PRECAUTIONS, AND ADVERSE EVENTS in the final draft labeling (Information for Use).

Post-approval Requirements and Restrictions: See Approval Order